

K001387 I-STAT PORTABLE CLINICAL ANALYZER, MODEL 300Oct 5, 2000
156 days to decisionK001387 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k001387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	May 2, 2000
Decision date	Oct 5, 2000
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I-Stat Corp.
Location	Princeton, NJ, US
Contact	PAUL VANDERWERF
510(k) history	14 submissions · 14 cleared · 1989-2001

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